Albumin (Human) 5% Solution, USP

Albumin (Human) 5% Solution, USP, for intravenous injection

TRADE NAME	Albumin (Human) 5% Solution, USP
PRODUCT COMPOSITION	**Medicinal Ingredient:** Albumin (Human) 5% **Nonmedicinal Ingredients:** Sodium caprylate (0.08 mmol/g albumin) and acetyltryptophan (0.08 mmol/g albumin). Contains no preservative. Low aluminum content (≤ 200 µg/L).
ALTERNATIVES	**Non-blood product:** Artificial colloid or crystalloid solutions (depending on the clinical situation of the individual patient, according to current therapeutic guidelines and recommendations)[1]
	Blood product: N/A
DOSAGE	The volume administered should be adapted to the response of the individual patient. The infusion rate must be adjusted to individual requirements, based on initial assessment and monitoring of the patient's status. It should normally not exceed 5 mL/minute. • **Hypovolemic Shock:** The volume infused should be related to the estimated volume deficit and the speed of administration adapted to the response of the patient. • **Burn Therapy:** After a burn injury (usually beyond 24 hours) there is a close correlation between the amount of albumin infused and the resultant increase in plasma colloid osmotic pressure. The aim should be to maintain the plasma albumin concentration in the region of 2.5 g ± 0.5 g per 100 mL with a plasma oncotic pressure of 20 mmHg (equivalent to a total plasma protein concentration of 5.2 g per 100 mL). This is best achieved by the intravenous administration of Albumin (Human), usually as Albumin (Human) 25%. The duration of therapy is decided by the loss of protein from burned areas and in the urine. • **Cardiopulmonary Bypass:** Although the limit to which the hematocrit and plasma protein concentration can be safely lowered has not been defined, it is common practice to adjust the albumin and crystalloid pump prime to achieve a hematocrit of 20% and a plasma albumin concentration of 2.5 g per 100 mL in the patient. Refer to Product Monograph (DOSAGE AND ADMINISTRATION) for complete information.[1]
ADMINSTRATION	• Administer by intravenous infusion. • The choice between the use of Albumin (Human) 5% and Albumin (Human) 25% depends upon whether or not the patient requires primarily a higher colloid osmotic activity (Albumin (Human) 25%). • Swab stopper top immediately with a suitable antiseptic prior to entering vial. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. • Dispensing pins or needles up to 16 gauge should be used, and should only be inserted within the stopper area delineated by the raised ring. The stopper should be penetrated perpendicular to the plane of the stopper within the ring. • Solutions which have been frozen should not be used. Do not use if turbid. Do not begin administration more than 4 hours after the container has been entered. Partially used vials must be discarded. Vials which are cracked or which have been previously entered or damaged should not be used, as this may have allowed the entry of microorganisms. • Albumin solutions must not be diluted with sterile water for injection - there exists a risk of potentially fatal hemolysis and acute renal failure from the use of sterile water for injection as a diluent. Acceptable diluents for Albumin 5% Solution USP include 0.9% sodium chloride or 5% dextrose in water. Refer to Product Monograph (DOSAGE AND ADMINISTRATION) for complete information.[1]

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CLINICAL/ DIAGNOSTIC MONITORING	• Patients should be monitored against the possibility of circulatory overload or hypervolemia. • Blood coagulation parameters, the hematocrit and serum electrolytes should be monitored when a large volume of Albumin (Human) 5% Solution, USP is administered. • The rapid rise in blood pressure which may follow the administration of a colloid with positive oncotic activity necessitates careful observation to detect and treat severed blood vessels which may not have bled at the lower blood pressure. Refer to Product Monograph (WARNINGS AND PRECAUTIONS) for complete information.[1]

CLINICAL INDICATIONS	The oncotic and colloid properties of Albumin (Human) 5% Solution, USP are used to restore and maintain circulating blood volume, when needed, and when the use of a colloid is appropriate. Albumin (Human) 5% Solution, USP is primarily used in the treatment of shock associated with hemorrhage, surgery, trauma, burns, and bacteremia.
	• **Emergency Treatment of Hypovolemic Shock:**
	  • Albumin (Human) 5% is iso-oncotic with normal plasma and on intravenous infusion will expand the circulating blood volume by an amount approximately equal to the volume infused. In conditions associated mainly with a volume deficit, albumin is best administered as Albumin (Human) 5%; but where there is an oncotic deficit, Albumin (Human) 25% may be preferred.
	  • Removal of ascitic fluid from a patient with cirrhosis may cause changes in cardiovascular function and even result in hypovolemic shock. In such circumstances, the use of albumin infusion may be required to support the blood volume.
	• **Burn Therapy:** During the first 24 hours after sustaining thermal injury, large volumes of crystalloids are infused to restore the depleted extracellular fluid volume. Beyond 24 hours Albumin (Human) 25% may be preferred for this purpose.
	• **Cardiopulmonary Bypass:** Preoperative dilution of the blood using albumin and crystalloid.
	• **Acute Liver Failure:** In the uncommon situation of rapid loss of liver function, with or without coma, administration of albumin may serve the double purpose of supporting the colloid osmotic pressure of the plasma as well as binding excess plasma bilirubin.
	• **Sequestration of Protein Rich Fluids:** In conditions such as acute peritonitis, pancreatitis, mediastinitis, and extensive cellulitis, the magnitude of loss into the third space may require treatment of reduced volume or oncotic activity with an infusion of albumin.
	Refer to Product Monograph (INDICATIONS AND CLINICAL USE) for complete information.[1]

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SPECIAL CONSIDERATIONS	• Products made from human plasma may contain infectious agents, such as viruses, that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by inactivating and/or removing certain viruses. Despite these measures, such products can still potentially transmit disease. There is also the possibility that unknown infectious agents may be present in such products. Individuals who receive infusions of blood or plasma products may develop signs and/or symptoms of some viral infections, particularly hepatitis C. Based on effective donor screening and product manufacturing processes, this product carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob Disease (CJD), including variant Creutzfeldt-Jakob disease (vCJD), also is considered extremely remote. No cases of transmission of viral diseases or CJD, including vCJD, have ever been identified for albumin. • The physician should discuss the risks and benefits of this product with the patient, before prescribing or administering to the patient. • In hemorrhage, the administration of albumin should be supplemented by the transfusion of whole blood to treat the relative anemia associated with hemodilution. When circulating blood volume has been reduced, hemodilution following the administration of albumin persists for many hours. In patients with a normal blood volume, hemodilution lasts for a much shorter period. Refer to Product Monograph (WARNINGS AND PRECAUTIONS) for complete information.[1]
CONTRAINDICATIONS	• Albumin (Human) 5% Solution USP should not be given to patients who are hypersensitive to albumin or to any ingredient in the formulation or component of the container. • Albumin (Human) 5% should not be given to patients at special risk of developing circulatory overload (i.e., those with a history of congestive cardiac failure, renal insufficiency or stabilized chronic anemia). Refer to Product Monograph (CONTRAINDICATIONS) for complete information.[1]
STORAGE CONDITIONS	Store at temperatures not exceeding 30 °C. Do not freeze. Do not use after expiration date. The product should be used within 4 hours after the container has been entered.
REFERENCES	1. Product Monograph - Albumin (Human) 5% Solution, USP, January 25, 2018